DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1936]

Establishment of a Public Docket; Electronic Cigarettes and the Public Health Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for data, information, and comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products, is establishing a public docket in conjunction with the first public workshop to gather scientific information about electronic cigarettes (e-cigarettes) as announced in Docket No. FDA-2014-N-0001-0079. Regardless of attendance at the public workshop, interested parties are invited to submit comments, supported by research and data, regarding electronic cigarettes and the public health.

DATES: Submit written or electronic comments by April 15, 2015.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, email: workshop.CTPOS@fda.hhs.gov.
I. Background

On September 17, 2014, FDA announced a public workshop to gather information about e-cigarettes and the public health (Electronic Cigarettes and the Public Health; Public Workshop; 79 FR 55815, September 17, 2014, Docket No. FDA-2014-N-0001). The focus of the workshop is product science (specifically device designs and characteristics, and e-liquid and aerosol constituents), product packaging, constituent labeling, and environmental impact. FDA intends to follow the first workshop with two additional e-cigarette workshops; one on individual health effects and one on population health effects. As stated in the Federal Register notice of the public workshop, the workshops are not intended to inform the Agency’s deeming rulemaking. The workshops are intended to better inform FDA about these products. Should the Agency move forward as proposed to regulate e-cigarettes, additional information about the products would assist the Agency in carrying out its responsibilities under the law.

II. Submission of Comments

Regardless of attendance at the public workshop, interested parties are invited to submit comments, supported by research and data, regarding e-cigarettes and the public health. Information related to workshop presentations and discussion topics, including specific questions to be addressed at the workshop, can be found at http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm.

Interested persons may submit either electronic comments to this docket at http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be
seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: November 25, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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